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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/866,927	05/30/2001	Robert H. Getzenberg	076333-0240	6351

22428 7590 06/25/2003

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EXAMINER

HELMS, LARRY RONALD

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 06/25/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/866,927

Applicant(s)

GETZENBERG, ROBERT H.

Examiner

Larry R. Helms

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8-11 and 13-24 is/are pending in the application.
- 4a) Of the above claim(s) 2-6, 8, 9 and 13-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 10, 11 and 19-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

1. Claims 7 and 12 have been canceled.  
Claims 1 and 10 have been amended.  
Claims 19-24 have been added.
2. Claims 2-6, 8-9, 13-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions. Election was made in Paper No. 8.
3. ~~The text of those sections of Title 35 U.S.C. code not included in this office action~~ can be found in a prior Office Action.
4. The following Office Action contains some NEW GROUNDS of rejection necessitated by amendment.

#### Rejections Withdrawn

5. The rejection of claims 1, 10 and 11 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendments to the claims and arguments.
6. The rejection of claims 1, 10, 11 under 35 U.S.C. 112, first paragraph is withdrawn in view of the amendments to the claims.
7. The rejection of claims 1, and 10 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is withdrawn in view of the amendments to the claims.

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8. The rejection of claims 1, 10, 11 under 35 U.S.C. 102(b) as being anticipated by Briggman et al (Proceedings of the American Association for Cancer Research, Vol. 35 p15, #89, March 1994) as evidenced by Stedman's Medical Dictionary 1995, Williams and Wilkins is withdrawn in view of arguments.

***The following are some NEW GROUNDS of rejections***

***Claim Rejections - 35 USC § 112***

9. Claims 1, 10-11, 19-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 has been amended to recite that BLCA-6 has a molecular weight of about 31 kD. In the previous Office action the art of Getzenberg et al (Cancer Res. 56:1690-4, 1996) was evidenced that there is a discrepancy between the MW of the BLCA-6 protein, 22 vs. 31. In the response to this a declaration by Dr. Getzenberg was provided (see paper #14). The declaration has been carefully considered but is deemed not to be persuasive. The declaration is unsigned but even if it was signed it would not be persuasive. The declaration states that the BLCA-6 protein of Getzenberg et al has a molecular weight of 31 kD and would inherently have this property. The error in the molecular weight was given in table 2 of the reference and in Figure 1B a silver stained gel shows the BLCA-6 protein above the 29 kD molecular marker. In response to this argument, there is nothing in the declaration stating that the BLCA-6

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protein in the specification is the same as that in the Getzenberg et al reference. Also the picture of the gel in the Getzenberg et al reference is still not very clear. In addition, it is still unclear what the molecular weight is because in the response filed 4/14/03, the response states that "whereas the claimed antibody specifically binds to BLCA-6 protein having a much lower molecular weight (about 22 kDa)". Therefore, it is not clear what the molecular weight of the protein is. In addition, the specification does not have the silver stained gel or any support for the BLCA-6 protein being 31 kDa.

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10. Claims 1, 10-11, 19-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn to an antibody that binds to BLCA-6 having a molecular weight of about 31 kDa and a pI of about 8 wherein the BLCA-6 is in cancerous bladder cells but absent in normal bladder cells. Further claimed is the antibody is directed to SEQ ID NO:4 and is monoclonal and an antigen binding fragment and the antibody is labeled.

The specification teaches BLCA-6 is 22 kD and a pI of 8 and a sequence of SEQ ID NO:4 (see page 33). The specification does not teach an antibody to a 31 kDa protein. One skill in the art would not be able to make and use the invention because the specification does not teach a 31 kDa protein. In addition a person reading the

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specification would only conclude that BLCA-6 is 22 kDa and a pI of 8 and comprise a sequence of SEQ ID NO:4. With these three facts a skilled artisan would not be able to make the claimed invention. Although there is an indication (in the prior art and the declaration of Getzenberg) that the molecular weight is incorrect, there is nothing from the specification as filed to indicate that this is true. One could also equally argue that the pI or the sequence is incorrect.

Thus, the specification does not describe the invention to enable one skill in the art to make and use the invention.

### ***Priority***

11. Due to the new matter and enablement rejections above the claims in the instant application are granted the priority date of the instant application, 5/30/2001.

### ***Claim Rejections - 35 USC § 102***

12. Claims 1, 10-11, 20, 24 are rejected under 35 U.S.C. 102(b) as anticipated by Getzenberg et al (Cancer Research 56:1690-4, 1996).

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The claims recites an antibody that specifically binds to a nuclear matrix protein, BLCA-6, of MW 31kDa and pI of 8 and a sequence of SEQ ID NO:4, wherein the nuclear matrix protein is present in cancerous bladder cells but absent in normal bladder cells and is not elevated in subjects afflicted with cystitis.

Getzenberg et al teach nuclear matrix proteins which are present in bladder cancer cells and not in normal bladder cells (see Table 2 for BLCA-6) and the proteins have been isolated and are being used to raise antibodies to the proteins (see pages 1693-4). It would be inherent that the protein of Getzenberg et al is also not elevated in patients with cystitis and has the sequence of SEQ ID NO:4.

### ***Claim Rejections - 35 USC § 103***

13. Claims 1, 10-11, 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Getzenberg et al (Cancer Research 56:1690, 1994) as applied to claims 1, 10-11, 20, and 24, and further in view of Coffey et al (U.S. Patent 6,030,793, priority to 2/93).

Claims 1, 10-11, 20 and 24 have been described supra. Claims 19, 21-23 recite wherein the antibody is a fragment and the antibody is labeled with a therapeutic or radioisotope.

Getzenberg et al has been described supra. Getzenberg et al does not exemplify the production of the antibody or a fragment or a label. These deficiencies are made up for in the teachings of Coffey et al.

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Coffey et al teach antibodies to NMP and the antibody can be labeled with a therapeutic or radioisotope (see column 16, lines 4-40).

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to have produced an antibody to the protein of BLCA-6 of Getzenberg et al for imaging or therapy as taught by Coffey et al

One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success to have produced an antibody to the protein of BLCA-6 of Getzenberg et al for imaging or therapy as taught by Coffey et al because Getzenberg et al teach that the protein was isolated and antibodies were made to the protein and Coffey et al teach NMP can be used in diagnosis by using antibodies to the proteins and labeling the antibodies. Thus, it would have been obvious to produce antibodies to BLCA-6 of Getzenberg et al for diagnosis of cancer by detection or therapeutic treatment by labeling the antibodies.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

### ***Conclusion***

14. No claim is allowed.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP



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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

17. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the

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Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242.

Respectfully,

Larry R. Helms Ph.D.

703-306-5879



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